

February 19, 2008

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 08-02

Subject: Availability of *Clostridium perfringens* Type A Standard Antitoxin and Toxin

To: VS Management Team (VSMT)
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants
Area Veterinarians in Charge, VS
State Veterinarians

I. PURPOSE

This notice informs interested parties that the Center for Veterinary Biologics (CVB) is making available *Clostridium perfringens* Type A (alpha) Antitoxin Lot IRP 538 (06) and *Clostridium perfringens* Type A (alpha) Toxin Lot IRP 560-07. Manufacturers of *Clostridium perfringens* Type A products should use the new standard antitoxin and standard toxin in potency testing. These new standards replace, without a phase-in period, *Clostridium perfringens* Type A (alpha) Antitoxin Lot IRP 426 and *Clostridium perfringens* Type A (alpha) Toxin Lot IRP 532 (06).

II. BACKGROUND

The CVB remains committed to supplying references and reagents to assist in the regulatory control of U.S. veterinary biologics, especially where the CVB is the sole source of supply. The CVB has completed the process of establishing and validating new *Clostridium perfringens* Type A (alpha) Antitoxin and *Clostridium perfringens* Type A (alpha) Toxin. These references are now available to manufacturers of *Clostridium perfringens* Type A.

III. ACTION

Clostridium perfringens Type A (alpha) Antitoxin Lot IRP 538 (06) and *Clostridium perfringens* Type A (alpha) Toxin Lot IRP 560-07 are available upon request from the Center for Veterinary Biologics and should be used, upon receipt, in place of *Clostridium perfringens* Type A (alpha) Antitoxin Lot IRP 426 and *Clostridium perfringens* Type A (alpha) Toxin Lot IRP 532 (06). Please follow the procedures outlined in Veterinary Services Memorandum No. 800.97 for requesting either of these standards. Reagent Data Sheets, included with the references, provide instructions for dilution and storage and details concerning use.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics